

IN THE DRAWING

Please utilize the accompanying "Replacement" sheet containing FIG. 1 for the drawing of record, which is attached to both the "marked-up" and "clean" copies of the accompanying Substitute Specification. The "replacement" drawing is the drawing which formed a part of Applicants' corresponding P.C.T. application and which was published on December 21, 2000, as P.C.T. Publication No. WO 00/76395 A1.

The "Replacement" sheet containing FIG. 1 removes the circles surrounding the reference numerals included in the original P.C.T. drawing figure, but does not substantively amend the drawing figure over that published by W.I.P.O. under the P.C.T. and therefore contains no new matter.

In the first Office Action, the Examiner had requested the submission of a "Replacement" drawing for FIG. 1, which was not included with the file, but was available with the published P.C.T. application. The drawing figure attached to the Substitute Specification is respectfully submitted to meet the Examiner's requirements.

REMARKS

Reconsideration and withdrawal of the rejection and the allowance of all claims now pending in the above-identified patent application (*i.e.*, Claim 7-9) are respectfully requested in view of the foregoing amendments and the following remarks.

At the outset, it should be recognized that the present invention provides a method for recording into a memory of a cardiac recorder, which has a memory comprised of a manual trigger memory and an auto-trigger memory, with the auto-trigger memory being partitioned into a plurality of auto-triggering partitions, which avoids a false triggering of the auto-trigger which could then fill the memory with useless information, a common drawback inherent with prior art cardiac recorders having only a single type of memory used for both manual and auto-triggered ECG recordings.

More particularly, the presently claimed method includes the steps of continuously recording signals acquired from the manual trigger or the auto-trigger into the manual trigger memory and then copying those signals acquired from the auto-trigger from the manual trigger memory to a recording partition of the auto-trigger memory. By subdividing the memory of the cardiac event recorder into a separate manual trigger memory and an auto-trigger memory, the latter of which is further subdivided or partitioned, along with then copying the signals acquired from the auto-trigger from the manual trigger memory to a partition of the auto-trigger memory, a false triggering of the auto-trigger is avoided.

As will be explained in greater detail hereinafter, nowhere in the prior art is such a novel and effective method for recording signals into the memory of a cardiac event recorder, which prevents a false triggering of the auto-trigger, either disclosed or suggested.

By the present amendments, Applicants have cancelled all prior claims, which the Examiner re-numbered as Claims 1, 2 and 4-6 (Claim 3 being deemed to have been previously cancelled), and have substituted therefor new Claims 7-9, of which Claim 7 is now the single independent claim pending in the patent application. Claims 7-9 are directed to a method for recording into a memory of a cardiac event recorder and are submitted to be distinguishable over the prior art, as explained hereinafter.

New Claims 7-9 effect correction of the numbering error noted by the Examiner in the original set of claims, as well as addressing the Examiner's 35 U.S.C. §112, second paragraph, indefiniteness rejection of prior Claim 5 (now corresponding to new Claim 8), in which the Examiner had rejected Claim 5 as indefinite for lack of an antecedent basis for "the cycling mode."

In light of the entry of new Claims 7-9, withdrawal of the Examiner's 35 U.S.C. §112, second paragraph, indefiniteness rejection of the first Office Action is respectfully requested.

As part of the first Office Action, the Examiner objected to the layout of Applicants' Specification, the absence of the drawing figure that was included with Applicants'

corresponding P.C.T. application and the lack of an Abstract in conformance with U.S. practice. In order to address the various formal issues raised by the Examiner as to the U.S. Specification, a Substitute Specification (having both "marked-up" and "clean" copies) is being filed, pursuant to 37 C.F.R. §1.125. Acceptance of the Substitute Specification, which includes a "Replacement" drawing and an appropriate Abstract, is respectfully requested.

Turning now, in detail, to an analysis of the Examiner's prior art rejections of Applicants' claims, in the first Office Action the Examiner initially rejected prior Claims 1, 2, 4 and 6 (since substituted by new Claims 7-9) as being anticipated, pursuant to 35 U.S.C. §102(b), by Nau *et al.*, U.S. Patent No. 5,732,708, on the contention that Nau *et al.* substantially teaches that which is claimed by Applicants, wherein the manual trigger memory and the auto-trigger memory of the cardiac therapeutic device disclosed by Nau *et al.* operate in a wrapped/FIFO manner and with both memories of the device including multiple record storage areas.

In reply to the Examiner's anticipation rejection applying Nau *et al.*, this citation discloses a method for storing EGM and diagnostic data in a read/write memory of an implantable cardiac therapy device. Both types of data, *i.e.*, the EGM and the diagnostic data, derive from an auto-trigger. While Nau *et al.* is acknowledged as disclosing a memory configured into first and second memory blocks (Nau *et al.*, Col. 5, lines 38-55), the two memory blocks are for storing the EGM data and the diagnostic data, respectively. There is no teaching or suggestion in Nau *et al.* of acquired signals being recorded

into one memory block and then copied into a partition in a second memory block, as now claimed by Applicants.

Because Nau *et al.* fails to disclose or suggest, *inter alia*, the copying of signals from one memory block to a second memory block, *e.g.*, continuously recording in the manual trigger memory signals acquired from the manual trigger or auto-trigger, then copying the signals acquired from the auto-trigger from the manual trigger memory to a partition of the auto-trigger memory, Nau *et al.*, cannot reasonably be seen as either anticipating or rendering obvious the present invention, as now claimed. Accordingly, withdrawal of the Examiner's 35 U.S.C. §102(b) anticipation rejection applying Nau *et al.* is respectfully requested.

Separately, the Examiner rejected the subject matter of prior Claims 1, 2, 4 and 5 (now generally corresponding to new Claims 7-9) as also being anticipated, pursuant to 35 U.S.C. §102(e), by Lee *et al.*, U.S. Patent No. 6,496,715. It is the Examiner's position that Lee *et al.* substantially discloses Applicants' claimed invention, wherein Lee *et al.* teaches an implantable sensing device in which the manual trigger memory operates in a wrapped manner. Both memories in the device taught by Lee *et al.*, according to the Examiner, include multiple record storage areas with the manual recordings being two to three times the length of the automatic recordings.

In reply to the Examiner's anticipation rejection applying Lee *et al.*, as an initial matter, it is respectfully noted that the filing date of Lee *et al.*, U.S. Patent No. 6,496,715, is November 22, 2000. Lee *et al.* is acknowledged to claim continuation-in-part status

from an application having a filing date of August 27, 1999, which, in turn, claims divisional (*i.e.*, continuation) status from an earlier application filed March 3, 1998, which is indicated to have since issued as U.S. Patent No. 5,987,352. The present Applicants' priority claim dates back to their Australian patent application, filed June 10, 1999. Because it is unclear whether the subject matter being relied upon by the Examiner from U.S. Patent No. 6,496,715 also appears in U.S. Patent No. 5,987,352, the latter of which has a filing date antedating Applicants' priority claim, it is unclear whether the Examiner's application of U.S. Patent No. 6,496,715 is proper. Applicants will, therefore, reply to the Examiner's anticipation rejection applying *Lee et al.*, U.S. Patent No. 6,496,715, but wish to reserve their right to later object to the application of this reference if it is later discovered that the subject matter relied upon by the Examiner, as the basis for the anticipation rejection, did not appear in an earlier patent of *Lee et al.* having a filing date which antedates Applicants' priority claim of June 10, 1999.

With the foregoing reservation made of record, an analysis of *Lee et al.* finds that this citation refers to an implantable sensing device having both a manual trigger and an auto trigger. The memory of the sensing device taught by *Lee et al.* includes both manual and auto-triggers with the memory in *Lee et al.* being divided into working segments, as shown in FIG. 22 thereof; memory 111 is shown as being divided into segments 111a, 111b, 111c, 111d. According to *Lee et al.*, at Col. 23, lines 19-25, data from a manual trigger event is recorded in segments 111c, 111d (joined by looping arrow 122) to allow for a double-sized memory segment.

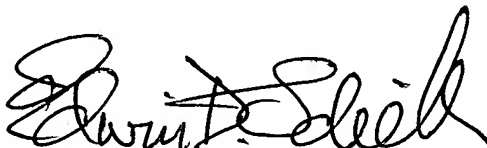
Lee *et al.*, as Nau *et al.*, fails to disclose or suggest the recording of an auto-trigger event in the manual trigger memory, followed by copying an event (*e.g.*, a cardiac event) into one of the auto-trigger recording partitions, as now claimed by the instant Applicants. Thus, withdrawal of the Examiner's 35 U.S.C. §102(e) anticipation rejection applying Lee *et al.* (assuming that Lee *et al.* would be properly citable against Applicants' claims) is respectfully submitted to be appropriate.

In view of the foregoing, it is respectfully submitted that all claims now pending in the above-identified patent application (*i.e.*, Claims 7-9) recite a novel and effective method for recording into the memory of a cardiac event recorder, which method avoids a false triggering of the auto-trigger, by subdividing the memory of the cardiac event recorder into a manual trigger memory and an auto-trigger memory, and continuously recording, in the manual trigger memory, signals acquired from the manual trigger or auto-trigger, then copying the signals acquired from the auto-trigger from the manual trigger memory to a partition of the auto-trigger memory, which is patentably distinguishable over the prior art. Accordingly, withdrawal of the outstanding objections and rejection

tions and the allowance of all claims now pending in the above-identified patent application are respectfully requested and earnestly solicited.

Respectfully submitted,

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- Enc.: 1. Petition for Two-Month Extension of Time;
2. Check for \$225.00 (Extension Fee); and,
3. Substitute Specification ("Marked-Up" and "Clean" Copies), pursuant to 37 C.F.R. 1.125, including "Replacement" drawing sheet (FIG. 1) and Abstract of the Disclosure in conformance with U.S. practice.

The Commissioner for Patents is hereby authorized to charge the Deposit Account of Applicants' Attorney (Account No. 19-0450) for any fees or costs pertaining to the prosecution of the above-identified patent application, but which have not otherwise been provided for.



*****"MARKED-UP" COPY*****

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: HARRY L. PLATT *ET AL.* ART UNIT: 3762

SERIAL NO.: 10/009,907

EXAMINER: F. P. OROPEZA

FILED: SEPTEMBER 19, 2002

TITLE: CYCLING EVENT AND AUTO-TRIGGER MEMORY HANDLING

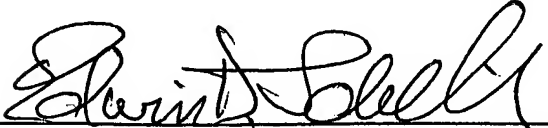
**DECLARATION OF NO "NEW MATTER" IN SUPPORT OF
SUBSTITUTE SPECIFICATION, PURSUANT TO 37 C.F.R. §1.125**

Hon. Commissioner for Patents
United States Patent and Trademark Office
P. O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

I, EDWIN D. SCHINDLER, am attorney-of-record for Applicants of the above-identified patent application and hereby affirm that I personally prepared the Substitute Specification for the instant patent application and, pursuant to 37 C.F.R. §1.125(b)(1),

I hereby certify that this paper is being deposited this date with the U.S. Postal Service as First Class Mail addressed to: Hon. Commissioner for Patents, United States Patent and Trademark Office, P. O. Box 1450, Alexandria, Virginia 22313-1450.


Edwin D. Schindler, Reg. No. 31,459

October 21, 2005

Date

state that I have not knowingly added any new matter to the application via the Substitute Specification, and that all of the amendments entered in the Substitute Specification are directed solely to matters of form and clarification of existing subject matter not affecting the scope of the invention.

I hereby declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this statement is directed.

A handwritten signature in black ink, appearing to read "Edwin D. Schindler", written over a horizontal line.

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CYCLING EVENT AND AUTO-TRIGGER MEMORY HANDLING

BACKGROUND OF THE INVENTION

Technical Field of the Invention

The present invention relates to the field of monitoring a cardiac patient's electrical cardiac activity by means of a cardiac event recorder and, in particular, to the memory handling of such cardiac event recorders.

BACKGROUND OF THE INVENTION

Description of the Prior Art

Cardiac event recorders usually currently known to the prior art generally have only one type of memory used for both manual and auto-triggered ECG recordings. Signal artifacts and noise can inadvertently cause a false triggering of the auto-trigger with such prior art devices and, thus, fill the memory with useless information.

It would be advantageous to provide a method and apparatus which prevents the memory of cardiac event recorders from being filled with useless information[[.]] resulting from a false triggering of the auto-trigger.

OBJECT OF THE INVENTION

SUMMARY OF THE INVENTION

It is, therefore, an object of the present invention to provide a method and

apparatus for the recording of an ECG which substantially overcomes or ameliorates the above-mentioned disadvantages by preventing memory overflow.

~~DISCLOSURE OF THE INVENTION~~

According to one aspect of the present invention, there is disclosed a method of recording into memory of a cardiac event recorder, said method including the steps of subdividing the memory into two parts~~[[,]]~~ with the two parts being a manual trigger memory and an auto-trigger memory~~[[,]]~~. Further, partitioning the auto-trigger memory into a plurality of auto-trigger recording partitions, whereby in the event of a manual trigger, acquired signals are recorded continuously in said manual trigger memory and in the event of an auto-trigger, acquired signals are recorded continuously in said manual trigger memory and then copied into one of said plurality of auto-trigger recording partitions

Preferably, the recording is done in cycling mode whereby the signal is continuously recorded in the manual memory, thus providing a segment of pre-event recording prior to the manual trigger, which records information for a predetermined length of time.

Preferably, if the recording is initiated by the auto-trigger, the cycling mode is not terminated or interrupted.

Preferably, at least two manual trigger recordings are able to be stored in the manual memory.

Preferably, the manual trigger recordings are about 2 to 3 times longer than the auto-trigger recordings.

~~BRIEF DESCRIPTION OF THE DRAWINGS~~

BRIEF DESCRIPTION OF THE DRAWING FIGURES

The present invention will now be described with reference to the accompanying drawing in which:

Fig. 1 is a diagram showing the memory of the cardiac event recorder.

~~BEST MODE OF CARRYING OUT THE INVENTION~~

DETAILED DESCRIPTION OF THE DRAWING FIGURES AND PREFERRED EMBODIMENTS

When recording an ECG using a cardiac event recorder (not illustrated), the data is recorded into RAM 10, which is generally recorded cyclically, *[[ie]] i.e.*, when the memory is full, the data overflows and records over the previously recorded data.

The RAM 10 is subdivided into two parts, *[[ie]] i.e.*, a manual trigger memory 11 and an auto-trigger memory 12. The auto-trigger memory 12 is further partitioned into a number of auto-trigger memory recordings 13.

In this cyclic recording mode, the data is continuously recorded into the manual trigger memory 12 and, thus, when a manual trigger is received, this fact is recorded.

The data recorded after a manual trigger is then stored in the manual trigger memory 11

with at least two manual triggered recordings being stored in the manual memory. In this cyclic memory mode, a segment of pre-event recording is also stored in the manual memory 11.

If an auto-trigger function initiated the trigger, the cycling mode is not terminated or interrupted (unlike the manual trigger.)[[.]] After the duration of the auto-triggered event, which is recorded in the manual memory 11, it is copied into one of the partitions 13 of the auto-trigger memory 12.

The foregoing describes only one embodiment of the present invention, and modifications obvious to those skilled in the art can be made thereto without departing from the scope of the present invention.

WHAT IS CLAIMED IS:

Claims 1-6 (canceled)

7. (new) A method for recording into a memory of a cardiac event reader, said memory being subdivided into a manual trigger memory and an auto-trigger memory with said auto-trigger memory being partitioned into a plurality of auto-trigger recording partitions, said method comprising the steps of:

continuously recording signals acquired from the manual trigger or the auto trigger in the manual trigger memory; and,

copying said signals acquired from the auto-trigger from the manual trigger memory to a recording partition of said plurality of auto-trigger recording partitions of the auto-trigger memory.

8. (new) The method for recording into a memory of a cardiac event recorder according to Claim 7, wherein said step of continuously recording signals from said manual trigger or said auto-trigger is carried out in a cycling mode.

9. (new) The method for recording into a memory of a cardiac event recorder according to Claim 7, wherein said manual trigger memory stores at least two said signals acquired from said manual trigger.



ABSTRACT OF THE DISCLOSURE

A method for recording into a memory of a cardiac event recorder, in which the memory of the cardiac event recorder includes a manual trigger memory and an auto-trigger memory, with the auto-trigger memory being partitioned into a plurality of auto-trigger recording partitions, the method includes the steps of continuously recording signals, in the event of a manual trigger, acquired from the manual trigger or the auto-trigger in the manual trigger memory, and copying the signals acquired from the auto-trigger from the manual trigger memory to a partition of the auto-trigger memory.

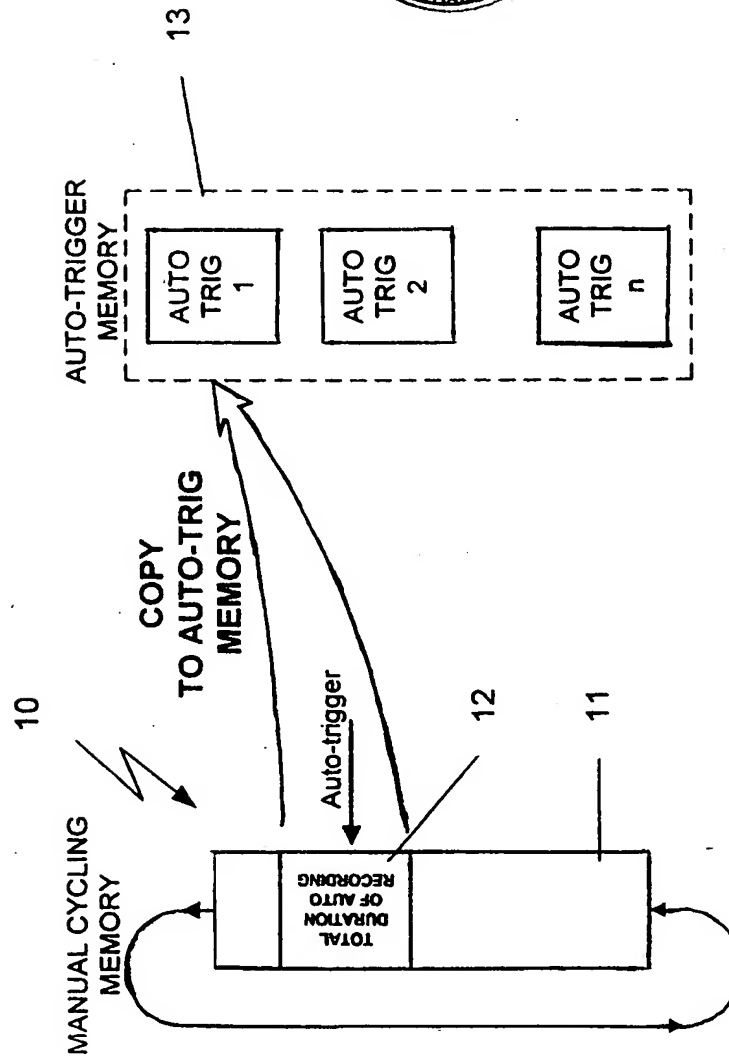


Fig 1